

REMARKS/ARGUMENTS

Claims 14-28 were pending prior to this Amendment. Independent claim 14 is amended to clarify that the restoration agent is selected to reverse the effects of an anticoagulant already contained in received liquid, with support found in the specification at page 76, lines 17-19 of Applicants' specification. Independent claim 22 is amended to clarify that the filter has a porosity to collect solids (such as blood clot materials) but allow liquid to pass, with support found at page 77, first full paragraph. Claim 29, which depends from claim 14, is added to clarify that the activation agent can be a contact activator used to initiate thrombin expression (with the thrombin expression feature already included in independent claim 22). Claim 18 is canceled to expedite prosecution and to address an objection to the drawings.

The use of a restoration agent and an activation agent to reverse an anticoagulant to initiate clotting in a collection chamber and to then express thrombin is not shown anywhere in the cited art as the devices in the cited art are addressing the desirability of preventing clotting in blood sample syringes.

No new matter is added by these amendments, and claims 14-17 and 19-29 remain for consideration by the Examiner.

A. Finality of Office Action

The October 10, 2003 Office Action was made final. However, the Examiner stated in the Response to Arguments that the Applicants' arguments in their prior response "are moot in view of the new ground(s) of rejection." The new grounds of rejection were not necessitated by Applicants' amendment which was supported by the originally filed claims. The new grounds of rejection also was not based on information submitted by Applicants in an IDS filed under 37 CFR 1.97(c). In contrast, the rejection was based on 4 new references that had previously not been reviewed by Applicants.

Hence, Applicants request that the finality of the October 10, 2003 Office Action be reconsidered, and the claim amendments provided in this Amendment be entered and the following remarks fully considered. See, MPEP 706.07(a) for further discussion of when a final rejection is improper on second or later actions.

B. Objection to the Drawings

The Office Action objected to the drawings under 37 CFR 1.83(a) indicating the every feature specified in the claims must be shown. In particular, the Examiner requested that the mixing chamber, the filter, and the restoration agent be shown or canceled from the claims. Claim 18 has been canceled which contained the mixing chamber element. The filter of claim 15 is shown in Figure 60 (at least) with element 958 and the filter of claim 22 is shown in Figure 60 with element 953.

The restoration agent of claims 14 and 23 is not specifically shown in Figure 60 but per the specification the agent may be the vessel itself (shown as element 952) or may be an agent that would be in the vessel 952. The specification in the second full paragraph on page 76 describes in detail the restoration agent, and it is not required for the understanding of the invention that it be shown in Figure 60. The restoration agent is shown in Figures 62 and 63 as "ADD Ca++" as an exemplary restoration agent that reverses an anticoagulant and initiates clotting. Hence, 37 CFR 1.83(a) is satisfied for the restoration agent as this section of the regulations does not require an element be shown or labeled in every figure in which it might appear.

C. Rejections Under 35 U.S.C. § 103

In the October 10, 2003 Office Action, claims 14-28 were rejected as being unpatentable over U.S. Patent No. 6,197,194 ("Whitmore") in view of U.S. Patent No. 5,807,344 ("Iwasaki"). The rejection of claims 14-17 and 19-28 are traversed based on the following remarks.

Claim 14 is directed to a platelet gel dispenser that comprises "a restoration agent and an activation agent positioned within the chamber of the

first vessel, wherein the agents are positioned within the chamber prior to receiving the liquid and wherein the restoration agent at least partially reverses effects of an anticoagulation agent in the received liquid." The Office Action indicates that Whitmore "fails to disclose ...a restoration agent...and an activation member within the vessel." Iwasaki is said to overcome this deficiency in the teaching of Whitmore by disclosing "a syringe with a restoration agent such as calcium salt, an activation agent such as glass wool, plastic, or silica aluminum..." Because Iwasaki fails to teach either the restoration agent or the activation agent let alone their combination in a single vessel, Claim 14 is believed allowable over this combination of references.

Specifically, Iwasaki is addressing the need for a blood gas syringe 10 that is effective for collecting blood from a patient without allowing air to collect in the sampled blood or allowing the blood to clot in the syringe 10. To avoid clotting, "the syringe 10 preferably also includes a carrying device having an anticoagulant, such as heparin, provided thereon. To overcome free ionized calcium binding, yet provide adequate sample anticoagulation, the approximate heparin unit amount per 2.5 cc syringe is 8 units." See, col. 4, lines 22-27. Hence, the Iwasaki device functions very differently than the claimed dispenser which includes a restoration agent that "reverses effects of an anticoagulation agent in the received liquid." The Office Action points to the "entire reference" for the teaching of the restoration agent and the activation agent, but Applicants could find absolutely no teaching of either a restoration agent or an activation agent, but instead only found the teaching of an anticoagulant which fails to suggest either of the claimed agents and in fact, teaches away from their use.

Claims 15-17 and 19-21 depend from claim 14 and are believed allowable for at least the reasons for allowing claim 14. Further, claim 16 calls for valving means "for selecting concurrent flow to the first and second liquid lines or non-concurrent flow to the first and second liquid lines." The Examiner appears to be taking official notice of the valving means, and Applicants traverse this use of official notice and request Examiner to provide

a specific reference showing such a valving means used in conjunction with the other claimed elements of claim 14. Claims 19 and 20 call for the restoration agent to be calcium salt, and Iwasaki teaches away from the addition of calcium which would cause clotting and is using heparin to prevent clotting. Claim 21 specifies what the activation agent may comprise to initiate thrombin expression in the liquid, and because Iwasaki is not addressing thrombin expression, it does not teach any of the activation materials. Again, because no specific cites were provided in the Office Action, Applicants are not sure where the Examiner believes any of these materials are believed to be shown in the syringe 10. For these additional reasons, these claims are believed allowable.

Independent claim 22 is directed to a dispenser that also includes an activating agent in the first vessel and is believed allowable over Whitmore and Iwasaki for the reasons provided with reference to claim 14. Further, the activating agent is specified to cause expression of thrombin in the liquid in the first vessel. Iwasaki provides no teaching that an activation agent for expression of thrombin should be included in the syringe 10. Further, claim 22 calls for a filter element in the first vessel that is configured for filtering solids but allowing the liquid to pass. Iwasaki teaches a filter 70 in the syringe 10, but the filter 70 "includes a material that allows for air to pass through it, while preventing liquid, such as blood, from passing through the filter member 70." See, col. 4, lines 8-11. Hence, this filter would not be useful in the claimed invention liquid must be allowed to pass while solids in the liquid are blocked. Further, in claim 22, the filter comprises an activating agent. The filter 70 of Iwasaki is not described as an activating device and the materials it comprises are not specifically discussed. Hence, the dispenser of claim 22 is not taught or suggested by the combination of Whitmore and Iwasaki.

Claims 23-28 depend from claim 22 and are believed allowable for at least the reasons for allowing claim 22. Further, claim 23 calls for a restoration agent to restore clot-forming in the liquid, which Iwasaki teaches against with its inclusion of an anticoagulant in its vessel 10. Claim 25 calls

for the filter to comprise glass wool, and Iwasaki teaches a very non-porous filter element 70 and hence, it is very unlikely that the filter 70 could be formed from glass wool that is typically relatively porous even when packed tightly.

In the Office Action, claims 14-28 were also rejected as being unpatentable over Whitmore in view of U.S. Patent No. 4,687,000 ("Eisenhardt"). This rejection is respectfully traversed based on the following remarks.

As discussed with reference to the Iwasaki reference, the Eisenhardt reference fails to overcome the deficiencies noted in the Office Action with Whitmore. Specifically, Eisenhardt, as was Iwasaki, is directed to a sampling receptacle for treating blood with an anticoagulant (see, for example, the title). As taught at col. 8, lines 42-46, a syringe chamber 14 is defined at the inner end of the cylinder 10 and "this chamber contains a disc-like carrier body 15, which contains an anticoagulant composition..." Clearly, Eisenhardt teaches away from claim 14 which calls for a restoration agent that "at least partially reverses effects of an anticoagulation agent in the received liquid" and claim 23 that calls for the restoration agent in the first vessel "for restoring a clot-forming process in the liquid in the first vessel." Hence, claim 14 and its dependent claims 15, 16, 18-21, and 29 and dependent claims 23 and 24 are allowable over this combination of references

Also, Eisenhardt fails to teach an activation agent in the vessel as called for in claim 14 and 22. The activation agent in claim 22 is specifically included as part of the filter in the vessel and causes expression of thrombin. Eisenhardt is only addressing the need for control over clotting in the cylinder 10 and fails to provide any teaching regarding thrombin creation. For this reason, claims 14 and 22 and those that depend from these independent claims are allowable over Whitmore and Eisenhardt. Further, the reasons for allowing the dependent claims provided with reference to Iwasaki are applicable to Eisenhardt.

Yet further, Applicants request that specific citations be provided for the teaching of claim elements in Eisenhardt rather than "the entire reference"

citation provided in the Office Action. This would allow Applicants to more easily discuss this reference; for example, it is not clear what portion of Eisenhardt the Examiner considered a filter within the vessel (item 15?) as called for in claim 22.

Additionally, in the Office Action, claims 14-28 were rejected under 103(a) as unpatentable over Whitmore in view of U.S. Patent No. 6,511,439 ("Tabata"). This rejection is traversed for the reasons provided for the Iwasaki reference, with these reasons not being repeated in full here.

Briefly, however, Tabata does not overcome the shortcomings of Whitmore because no restoration or activation agent is taught and in fact, an anticoagulant supply 5 is shown in Figure 1 which teaches away from the restoration agent of claim 14 that reverses the effects of an anticoagulant in the received liquid. Again, the Office Action merely cites the "entire reference," but Applicants were unable to find any discussion of restoration and activation agents as called for in claims 14 and 22.

Further, the Tabata filter 35 is gas permeable but blocks liquids and hence, Tabata teaches away from the dispenser of claim 22. The filter 35 is never discussed in Tabata as comprising an activating agent "for expressing thrombin" as called for in claim 22. Claims 15, 17, 18-21, and 23-29 depend from claims 14 and 22 and are believed allowable for the reasons for allowing the base claims. Additionally, the reasons provided for allowing these dependent claims with respect to the Iwasaki reference are applicable to the Tabata reference.

C. Conclusion

In view of all of the above, all pending claims are believed to be allowable over the art of record.

No fee is believed due with this submittal, but if any deficiency should exist, please charge Deposit Account 50-1123. Should any extension of time be required, please consider this a petition therefore and charge the required fee to Deposit Account 50-1123.

It is respectfully requested that a timely Notice of Allowance be issued in this case.

Respectfully Submitted,

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